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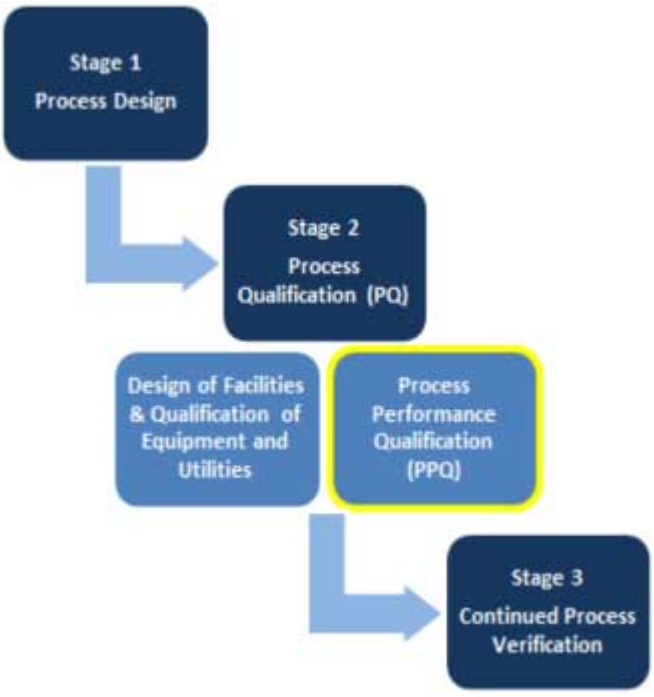
Process Performance Qualification: Selecting the Optimal Sampling Plan

By **Amored Amaya Sep 12, 2013 5:17 pm EDT**

Process validation is defined as the collection and evaluation of data from the process design stage through the commercial production that establishes scientific evidence that a process is capable of consistently delivering quality product and thereby also assuring reliability of supply. US Food and Drug Administration emphasizes that process validation should not be viewed as a one-time event, instead that a lifecycle approach should be applied linking product process and development, qualification of the commercial manufacturing process, and maintenance of the process in a state of control during routine commercial production. Sampling methodology becomes a key factor in carrying out process validation as it concerns monitoring and evaluating variability, especially in process qualification (Stage 2) and continued process verification (Stage 3). Current good manufacturing processes (cGMP) regulations specify that samples must: represent the batch under analysis and meet specifications and statistical quality control criteria as conditions of approval and release. Furthermore, the batch must meet its predetermined specifications. The Figure depicts the typical stages of process validation as defined by FDA. This review will indicate a few of the crucial steps involved in the process performance qualification (PPQ) stage as it applies to the regulation of medical devices (highlighted in in the Figure).

The PPQ is an important milestone within the product lifecycle. The approach to PPQ should be based on sound science, product, process understanding, and demonstrable controls. During this stage, the process design is evaluated to determine if th order to ensure that the total system performs as int dditional testing, and greater scrutiny of process pe cting the sampling plan for any given manufacturing pr ability of the process. The steps involved in selecting the op

Figure: Stages of Process Validation



percent defective (LTPD)

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